Policy for the use of Irradiated blood products

<table>
<thead>
<tr>
<th>SharePoint Location</th>
<th>General Policies and Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>SharePoint Index Directory</td>
<td>Haematology and Blood Transfusion</td>
</tr>
<tr>
<td>Sub Area</td>
<td>-</td>
</tr>
<tr>
<td>Key words (for search purposes)</td>
<td>Irradiated blood products, Transfusion</td>
</tr>
<tr>
<td>Central Index No</td>
<td>0662 v1</td>
</tr>
<tr>
<td>Endorsing Body</td>
<td>Clinical Governance Committee</td>
</tr>
<tr>
<td>Endorsement Date</td>
<td>September 2010</td>
</tr>
<tr>
<td>Review Date</td>
<td>September 2013</td>
</tr>
<tr>
<td>Lead author and designation</td>
<td>Dr Kanchan Rege</td>
</tr>
<tr>
<td>(if under review) Review led by</td>
<td>N/A</td>
</tr>
</tbody>
</table>
KEY POINTS: This policy -
- Applies to all staff with responsibility for prescribing and administering blood and blood components.
- Gives guidance on when and how to request Irradiated blood products
- This policy has been assessed using an equality impact assessment initial screening template and is deemed to meet current equality requirements. The equality impact assessment does take into account the refusal by some religions to have blood products. The screening template can be found in Appendix 3.
Background
In certain at risk patient groups, transfused donor lymphocytes that are compatible with
the recipient, but which recognise the recipient as foreign, can engraft and initiate
transfusion associated graft versus host disease (Ta-GvHD)

Affected patients can develop skin rashes, diarrhoea, abnormal liver function and bone
marrow failure. Death from infection usually occurs within 2-3 weeks of the transfusion.

The use of gamma or X ray irradiation (25 Gy) inactivates the donor T-Lymphocytes
whilst preserving the function of the other cells therefore preventing Ta-GvHD.

For at risk patients, all red cell, (except cryopreserved) platelet and granulocyte
transfusions should be irradiated. It is not necessary to irradiate fresh frozen plasma,
cryoprecipitate or fractionated plasma.

Since universal leucocyte depletion of blood products, there have been fewer reports of
Ta-GVHD. These guidelines, however, give an indication of best transfusion practice.

Purpose and scope of policy
To ensure that irradiated blood products are requested for and transfused to patients
who require them.

1 Definition of Terms
- Blood products- Any therapeutic product derived from human whole blood or
  plasma donations
- Irradiated blood component- Cellular blood component treated with 25 gray
  (Gy) gamma irradiation or Xray irradiation to inactivate lymphocytes that could
  cause graft-versus-host disease in a recipient.

2.1 Process
The issue of irradiated blood components to those patients who require them.

2.2 Content

2.2.1 Indications
- All transfusions from first or second-degree relatives, regardless of the
  patients’ immune status.
- HLA-selected platelets regardless of recipients immune status
- Intra-uterine transfusion – blood should be transfused within 24hours of
  irradiation
- Exchange transfusions where there has been a previous IUT or if the
donation is from a 1st or 2nd degree relative
CAUTION: You must refer to the intranet for the most recent version of this policy.

- Top-up transfusion in neonates only if previously a recipient of an intra-uterine or exchange transfusion.
- Bone marrow and stem cell transplant recipients from the time of conditioning treatment up to 3 months after transplant (autologous transplants) or 6 months (allogeneic transplants). It may be necessary to irradiate blood products for SCID patients for up to 2 years, and for patient with chronic GvHD if there is evidence of immuno-suppression
  NB – It is not necessary to irradiate red cells or platelets for children or adults with acute leukaemia, except for HLA matched platelets or donations from first or second-degree relatives
- Transfusion to bone marrow donors prior to or during harvest
- Autologous marrow or stem-cell donations in the 7 days prior to harvest
- Hodgkin’s disease
- Treatment with purine analogues (Fludarabine, Cladribine and Deoxycoformycin).
- Patients with the following congenital immunity deficiencies
  o SCID
  o 3rd and 4th arch/pouch syndrome (Di George’s)
  o Wiskott-Aldrich syndrome
  o Purine nucleoside phosphorylase deficiency
  o Cell-mediated immunodeficiency, not otherwise classified
  o Reticular dysgenesis
  o Adenosine deaminase deficiency
  o MHC Class I and II deficiency
  o Immunodeficiency with eosinophilia (Omenn’s syndrome)
  o Ataxia telangiectasia
  NB - There is currently no indication for the irradiation of blood for infants or children with HIV or AIDS, however this remains under review.

2.2.2 How to request irradiated blood products:
- Using the Anglia requesting system, the requirement for irradiated blood products should be indicated by clicking the yes button at the ‘special requirement’ option screen. The transfusion laboratory must also be informed by telephone of the requirement for irradiated blood products
- Once the requirement for irradiated blood products has been communicated to the Transfusion Laboratory, all further blood products issued will be irradiated until the Transfusion Laboratory is informed otherwise.
- The requirement for irradiated blood products must be noted in the Special Requirement box on the dedicated Blood and Blood Products prescription and Transfusion Record (see Appendix 1).
- Once the indication for irradiated blood products has been established, the patient should be provided with an appropriate card and encouraged to carry it at all times (see Appendix 2)
2.3 **Endorsement**
The policy will be approved by the Hospital Transfusion Committee.
Final endorsement will be by the Clinical Governance Committee.

2.4 **Distribution**
The policy will be recorded on SharePoint.
Staff will be made aware of the policy during induction and clinical update sessions, and via e Brief.

3. **Implementation**
3.1 The policy will be reviewed every three years or sooner if required in light of new evidence or statutory requirements.
3.2 The transfusion laboratory will maintain responsibility for ensuring Irradiated products are issued when requested appropriately, referring to laboratory SOP TRA-CC-TRA 001/09. This SOP is reviewed annually.
3.3 An audit of the requirement for Irradiated blood products to be noted in the ‘Special Requirement’ box on the dedicated Blood and Blood Products prescription and Transfusion Record will be performed to monitor compliance.
3.4 An audit to monitor the issue of Irradiated units to the patients which require them will be performed 6 monthly.
3.5 If there is any deviation from this policy, an incident form will be raised via DATIX, and the incident investigated by the transfusion operational management team and corrective and preventative actions implemented. If appropriate, a report will be made to SHOT and SABRE

**Glossary of Terms**
- Irradiated Blood Component: Cellular blood component treated with 25 Gray (Gy) Gamma or Xray irradiation to inactivate lymphocytes that could cause graft-versus-host disease
- SOP: Laboratory Standard Operational Procedure
- DATIX: Electronic Adverse event and near miss reporting form
- SHOT: Serious Hazards of Transfusion UK wide reporting system for adverse transfusion events and ‘near misses’
- SABRE: Serious Adverse Blood Reactions and Events This system allows reporters to electronically submit reports of serious adverse events or serious adverse reactions directly to the Medicines and Healthcare Products Regulatory Agency (MHRA)

**References**

CAUTION: You must refer to the intranet for the most recent version of this policy.


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Appendix 1 Prescription chart

Blood and Blood Products Prescription and Transfusion Record

<table>
<thead>
<tr>
<th>Addressograph or Hospital Number</th>
<th>Reason for transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
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<tr>
<td>Date of Birth</td>
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</tr>
<tr>
<td>Consultant</td>
<td></td>
</tr>
</tbody>
</table>

Red Cell Transfusion Code (see overleaf): R 1 2 3 4 5 6 7 8

Durotic to be given with transfusion: Yes/No

Hydrocortisone to be given with transfusion: Yes/No

Blood warmer to be used: Yes/No

All medication to be given with the transfusion must be prescribed on the patient's main prescription chart

Special Requirements (please tick)
None
Irradiated Blood
CMV negative

Name of Prescriber
Signature of Prescriber
Barcode Number

Please complete one line for each unit prescribed

<table>
<thead>
<tr>
<th>Date</th>
<th>Product</th>
<th>Amount</th>
<th>Infusion rate</th>
<th>Prescriber's Signature</th>
<th>Print Name &amp; Barcode No</th>
<th>Unit Serial No</th>
<th>Given by</th>
<th>Checked by</th>
<th>Date &amp; time unit started</th>
<th>Date &amp; time unit completed</th>
</tr>
</thead>
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</table>

If a reaction occurs please record:
Any symptoms observed

Name of Doctor informed of reaction: Informed by: Name & Signature

Transfusion laboratory informed by: Name & Signature

Transfusion Reaction form completed: Yes / No

Please record any comments, reasons and actions for any units stopped/wasted, early/late completion of units.
CAUTION: You must refer to the intranet for the most recent version of this policy.

Appendix 2
Irradiated Blood information leaflet and card

Information for patients needing irradiated blood
Including important patient card and patient record stickers

I am at risk of transfusion-associated graft-versus-host disease
If I need to have a blood transfusion, cellular blood components (Red Cells and Platelets) MUST BE GAMMA IRRADIATED

Please inform your blood transfusion laboratory

Please detach the above card, complete the details on the reverse and hand to the patient. This card must be shown to the patient's medical team before each transfusion.

This patient is at risk of transfusion-associated graft-versus-host disease
If this patient needs to have a blood transfusion, cellular blood components (Red Cells and Platelets) MUST BE GAMMA IRRADIATED

Please inform your blood transfusion laboratory

This patient is at risk of transfusion-associated graft-versus-host disease
If this patient needs to have a blood transfusion, cellular blood components (Red Cells and Platelets) MUST BE GAMMA IRRADIATED

Please inform your blood transfusion laboratory
**Appendix 3 Equality Impact assessment Form**

**Peterborough and Stamford Hospitals NHS Foundation Trust**

**STAGE ONE : Equality Impact Assessment screening form**

Assessing Functions/Policies for Relevance

<table>
<thead>
<tr>
<th>Blue boxes are to be filled in</th>
<th>Free text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow boxes - Click the box to select from the drop down list</td>
<td>Select from drop down box</td>
</tr>
</tbody>
</table>

Name of function / service / strategy / policy / project (activity) to be assessed: Policy for the use of Irradiated blood products

Name(s) of those completing this EqIA Screening form: Kaye Bowen Transfusion Coordinator

CBU / Department: Clinical Services

Date: 24 Feb 2010

Function/service/strategy/policy/project (activity) aim or purpose: To ensure that irradiated blood products are requested for and transfused to patients who require them.

Is this a new or existing activity: Existing activity
**CAUTION:** You must refer to the intranet for the most recent version of this policy.

<table>
<thead>
<tr>
<th>What are the intended results of this activity:</th>
<th>Reduce risk by ensuring that all patients who require irradiated blood products receive them.</th>
</tr>
</thead>
<tbody>
<tr>
<td>How will you measure the outcome of the activity:</td>
<td>Audit of patient and laboratory records.</td>
</tr>
<tr>
<td>Who is intended to benefit from the activity:</td>
<td>Patients and staff</td>
</tr>
<tr>
<td>Please identify any internal/external groups who have been consulted regarding this activity:</td>
<td>Hospital Transfusion Team. Hospital Transfusion Committee. National Blood and Transplant Service</td>
</tr>
</tbody>
</table>

Use the table below to identify whether the activity could/does have a positive impact, a negative impact or no impact at all on either any or all of the equality groups specified.

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>*Disability</th>
<th>Ethnicity / Race</th>
<th>Gender</th>
<th>Religion / Belief</th>
<th>Sexual Orientation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliminating unlawful/unjustifiable discrimination</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>Promoting equality of opportunity</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>Promoting positive attitudes and good community relations between and towards differing equality groups</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
</tbody>
</table>

Policy for the use of Irradiated blood products  
September 2010  
Index: 0662v1
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<table>
<thead>
<tr>
<th></th>
<th>Neutral</th>
<th>Neutral</th>
<th>Neutral</th>
<th>Neutral</th>
<th>Neutral</th>
<th>Neutral</th>
<th>Neutral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eliminating harassment or victimization</td>
<td></td>
<td></td>
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<tr>
<td>Encourage involvement and participation</td>
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<td></td>
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<tr>
<td>Eliminating health inequalities</td>
<td></td>
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</tr>
</tbody>
</table>

If the answer to any of the above is Positive or Negative then please complete the Stage Two Full Equality Impact Assessment form to avoid or address the potential adverse impact.

Decision to proceed (please select): No, we have decided that it is not necessary to carryout a full EqIA

Reason for decision: There are no aspects of the policy which could discriminate against any group

Executive Director/General Manager - I confirm that I have been briefed on the results of this impact assessment.

Name: Rob Heywood
Date: 14.9.10

Signature:

Please note the following:
It is an essential that this EqIA screening form is discussed by your management team and remains readily available for inspection. A copy should also be forwarded to the Communications team for publication on the Trusts internet site.
## Appendix 4 Compliance Monitoring

<table>
<thead>
<tr>
<th>Process to be monitored</th>
<th>How will compliance with the outlined process be monitored?</th>
<th>Frequency</th>
<th>By who?</th>
<th>If compliance gaps have been identified, who is responsible for creating an action plan, and ensuring implementation of required changes?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of trust prescription chart indicating need for irradiated components</td>
<td>Audit of prescription charts</td>
<td>Monthly</td>
<td>Clinical Audit department</td>
<td>Transfusion Operational Management Team</td>
</tr>
<tr>
<td>Requesting of irradiated negative products</td>
<td>Audit of patient and Laboratory records</td>
<td>6 monthly</td>
<td>Transfusion Laboratory staff and Transfusion Coordinator</td>
<td>Transfusion Operational Management Team</td>
</tr>
<tr>
<td>Issue of irradiated negative products</td>
<td>Audit of patient and Laboratory records</td>
<td>6 monthly</td>
<td>Transfusion Laboratory staff and Transfusion Coordinator</td>
<td>Transfusion Operational Management Team</td>
</tr>
<tr>
<td>Deviation from policy resulting in adverse event or near miss</td>
<td>Review of DATIX incident forms</td>
<td>Within 1 week of incident report</td>
<td>Transfusion Operational Management Team</td>
<td>Transfusion Operational Management Team</td>
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</table>
CAUTION: You must refer to the intranet for the most recent version of this policy.

Appendix 5
Summary and Audit Trail

Development process

<table>
<thead>
<tr>
<th>Title: Policy for the use of Irradiated blood products</th>
<th>Trustwide &amp; Healthcare Economy</th>
<th>Trustwide</th>
<th>CBU</th>
<th>Dept</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multidisciplinary</td>
<td>Medical Staff</td>
<td>X</td>
<td>Allied Health Professionals</td>
<td>Nursing/ Midwifery</td>
</tr>
</tbody>
</table>

Reason for Development: (e.g. planned review of existing document, patient complaint, critical incident, publication of new evidence, inconsistent practice, NICE Guidance)
To ensure awareness of importance of requesting blood components of correct specification

Development Lead: Dr Kanchan Rege Consultant Haematologist

Tel. Number: 4167 Email Address: Kanchan.Rege@pbh-tr.nhs.uk

Development Team Members:
- Martin Drury - Transfusion Laboratory Manager
- Kaye Bowen - Transfusion Coordinator

Key sources of evidence used in the development of the document or the method of achieving consensus where evidence is not available:
- National Blood Service Portfolio of Components and Guidance for their Clinical Use
- British Committee For Standards in Haematology guidelines on gamma irradiation of blood components for the prevention of transfusion associated graft-versus-host disease.

Consultation Process

Please list key Staff Members and Groups/Committees involved in the Consultation Process:
Hospital transfusion Team

Please identify committee(s) which will approve the policy (see flow chart for development):
Hospital Transfusion committee

Once this form has been completed it should be sent to the Compliance Officer with the final copy of the policy.